

availability of Compliance Policy Guide Sec. 540.370—Fish and Fishery Products—Decomposition (the CPG). The CPG provides guidance for FDA staff on decomposition in fish and fishery products.

**DATES:** Submit written or electronic comments on the CPG at any time.

**ADDRESSES:** Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

**FOR FURTHER INFORMATION CONTACT:** Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2300.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of July 18, 2008 (73 FR 41361), FDA announced the availability of draft CPG Sec. 540.370—Fish and Fishery Products—Decomposition and gave interested parties an opportunity to submit comments. The agency received no comments on the draft CPG but on its own initiative made a few editorial changes for clarification purposes. The CPG provides guidance for FDA staff on decomposition in fish and fishery products. The CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing this CPG as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on FDA's direct reference enforcement criteria related to decomposition in fish and fishery products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic

comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

#### **III. Electronic Access**

Persons with access to the Internet may obtain the CPG at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

Dated: January 12, 2009.

**Michael A. Chappell,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. E9-1142 Filed 1-21-09; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **Leadership Education in Neurodevelopmental and Other Related Disabilities MCH Training Program**

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of Class Deviation from Project/Budget Period Funding Policies.

**SUMMARY:** HRSA will provide 2 additional years of support in the absence of competition for one cohort of grants under the Leadership Education in Neurodevelopmental and Other Related Disabilities (LEND) MCH Training Program. HRSA will extend the project period to June 30, 2011, for the cohort of the LEND program expected to compete in fiscal year (FY) 2009, which would correspond to the sunset of the Combating Autism Act. Currently, there are 34 LEND grants split into two cohorts (17 each) with different end dates; one group is scheduled to compete in FY 2009 (Cohort A), and the other in FY 2011 (Cohort B). HRSA will

non-competitively extend with funds the 5-year project periods for those LEND grantees ending on June 30, 2009, for 2 additional budget periods at the same level of support for the same scope of activities which they received in FY 2008.

#### **SUPPLEMENTARY INFORMATION:**

##### **Intended Recipients of the Award**

Seventeen programs in the LEND cohort are expected to compete in FY 2009. These programs presently have active LEND grants: University of Iowa, Johns Hopkins University, University of Missouri, University of Nebraska, Dartmouth Hitchcock Medical Center, Albert Einstein College of Medicine, Children's Hospital of Pittsburgh, University of South Dakota, University of Vermont, Virginia Commonwealth University, West Virginia University, University of Massachusetts Medical School, Ohio State University, Vanderbilt University, Children's Research Institute, Indiana University, University of Oklahoma.

Amount of Individual Supplemental Awards: **Note:** These funding levels are expected to continue in FYs 2009 and 2010.

Grantee	FY 2008 award
University of Iowa .....	\$491,265
Johns Hopkins University .....	884,277
University of Missouri .....	393,012
University of Nebraska .....	412,663
Dartmouth Hitchcock Medical Center .....	451,964
Albert Einstein College of Medicine .....	491,265
Children's Hospital of Pittsburgh .....	393,012
University of South Dakota .....	432,313
University of Vermont .....	451,964
Virginia Commonwealth University .....	451,964
West Virginia University .....	439,825
University of Massachusetts Medical School .....	604,256
Ohio State University .....	393,011
Vanderbilt University .....	393,012
Children's Research Institute ...	393,012
Indiana University .....	481,440
University of Oklahoma .....	442,139

*Current Project Periods:* 7/1/04 through 6/30/09.

*Period of Supplemental Funding:* 7/1/09 through 6/30/11.

**Authority:** Combating Autism Act of 2006, Public Law No. 109-416, § 399BB(e)(1)(A), 120 Stat 2821, 2826 (2006).

*CFDA Number:* 93.110.

**FOR FURTHER INFORMATION CONTACT:** Laura Kavanagh; Branch Chief, MCH Training Program, Division of Research, Training and Education; Maternal and Child Health Bureau; (301) 443-2254.

*Justification for the Exception to Competition:* HRSA is ending the two cohort system for the following reason:

The Combating Autism Act of 2006 is scheduled to sunset in September of 2011. With this legislation, it is critical to have sufficient and accurate data to evaluate the progress of screening and diagnosing a greater number of children with autism spectrum disorder (ASD) and other developmental disabilities and assuring that they receive evidenced based services. A national evaluation will be conducted to contribute to the HHS Secretary's Report to Congress on progress related to ASD and other developmental disabilities as required by the Combating Autism Act. From a programmatic perspective, it is imperative to collect data from the same group of grantees over the project period to assess program goals as requested in the National Evaluation. By extending the project period for two additional years for the LEND cohort with the current project period ending date of June 30, 2009, MCHB will be able to collect common data elements from both LEND cohorts through the end of Combating Autism Act which sunsets in 2011. Doing so will help ensure that there will be a more cohesive and uniform collection of data being gathered and analyzed across both cohorts which will increase sample size and ultimately, data validity and study power. If it becomes necessary to hold a competition for the LEND cohort in FY 2009 and new applicants were to apply and be successful, there would be the potential for less uniformity in the data collection. It is crucial that there is as much meaningful data gathered in the remaining time available from both cohorts to ensure that the National Evaluation is an accurate reflection of the program activities.

Under this deviation, MCHB will provide the LEND grantees in LEND Cohort A, currently expected to compete in FY 2009, with the same amount of funds for the same scope of activities that they received in FY 2008 for both the FY2009 and 2010 budget periods.

Dated: January 13, 2009.

**Elizabeth M. Duke,**  
Administrator.

[FR Doc. E9-1236 Filed 1-21-09; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Multiscale Models of the Physiome.

*Date:* January 29–30, 2009.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)

*Contact Person:* Malgorzata Klosek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435-2211, [klosekm@csr.nih.gov](mailto:klosekm@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering, Integrated Review Group Biomedical Imaging Technology Study Section.

*Date:* February 2–3, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Guest Suites Doheny Beach, 34402 Pacific Coast Highway, Dana Point, CA 92629.

*Contact Person:* Lee Rosen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171, [rosenl@csr.nih.gov](mailto:rosenl@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Oncological Sciences Integrated Review Group, Tumor Microenvironment Study Section.

*Date:* February 2–3, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

*Contact Person:* Eun Ah Cho, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, (301) 451-4467, [choe@csr.nih.gov](mailto:choe@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences, Integrated Review Group, Musculoskeletal Tissue Engineering Study Section.

*Date:* February 2–3, 2009.

*Time:* 8 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

*Contact Person:* Jean D. Sipe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892, 301/435-1743, [sipej@csr.nih.gov](mailto:sipej@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Biology of Development and Aging Integrated Review Group, Development—2 Study Section.

*Date:* February 5, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The River Inn, 924 25th Street, NW., Washington, DC 20037.

*Contact Person:* Neelakanta Ravindranath, Ph.D., MVSC, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5140, MSC 7843, Bethesda, MD 20892, 301-435-1034, [ravindr@csr.nih.gov](mailto:ravindr@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Immunology Integrated Review Group, Innate Immunity and Inflammation Study Section.

*Date:* February 5–6, 2009.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

*Contact Person:* Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301-594-6375, [mcintyrt@csr.nih.gov](mailto:mcintyrt@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Infectious Diseases and Microbiology, Integrated Review Group, Clinical Research and Field Studies of Infectious Diseases Study Section.

*Date:* February 6, 2009.

*Time:* 8:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

*Contact Person:* Soheyla Saadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301-435-0903, [saadisoh@csr.nih.gov](mailto:saadisoh@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience, Integrated Review Group, Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* February 9–10, 2009.